DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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May 6, 2015

Shantou Xinghe Electrical Apparatuses Co., Ltd
% Mike Gu
Regulatory Affairs Manager
Guangzhou Osmunda Medical Device Technical Services., Ltd.
7th Floor, Jingui Business Building,
No. 982 Congyun Rd.,Baiyun District,
Guangdong, 510420
China

Re: K143585
Trade/Device Name: Electric Breast Pump
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered breast pump
Regulatory Class: II
Product Code: HGX
Dated: April 21, 2015
Received: April 23, 2015

Dear Mike Gu,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143585

Device Name
Electric breast pump

Indications for Use *(Describe)*
The electric breast pump is intended to express and collect milk from the mother's breast, to alleviate engorgement of the breast, maintain the ability of lactation, and provide mother's milk for future feedings when separation of mother and baby occurs. The device is intended for a single user, not for hospital use.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	2014/11/20
Submitter:	Shantou Xinghe Electrical Apparatuses Co., Ltd. Add: NO.8, Yi Road, Pingbei Industrial Zone, Chaoyang District, Shantou, 515100, Guangdong, China
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Secondary Contact Person:	Mike Gu Regulatory Affairs Manager Guangzhou Osmunda Medical Device Technical Service Co., Ltd. Tel: (+86)-20-6232 1333 Fax: (+86) -20-8633 0253
Device Trade Name:	Electric Breast Pump, Model XN-2201M1, XN-2201M3, XN-2206M2, XN-2207M1, XN-2209M1, XN-2210M2
Common/Usual Name:	Powered breast pump
Classification Names:	Powered breast pump
Regulation number	CFR 884.5160
Product Code:	HGX
Predicate Device(s):	K122474, LANSINOH Powered Electric Breast Pump
Reference Device(s):	K053052, Medela Swing The reference device is used as a reference for suction intensity. It has a 0～-0.033 MPa range of suction intensity, which is the same as the range of the proposed device.
Device Description:	The electric breast pump is designed and manufactured by the Shantou Xinghe Electrical Apparatuses Co., Ltd. It is intended to express and collect milk from breast from the mother's breast, to alleviate engorgement of the breast, maintain the ability of lactation, and provide mother's milk for future feedings when separation of mother and baby occurs. The device is intended for a single user, not for hospital use. Model XN-2201M1, XN-2201M3, XN-2206M2, XN-2207M1, XN-2209M1, XN-2210M2 are included in this submission. The electric breast pump imitates a baby's sucking action to express milk with help of Single-Chip Microcomputer. It has multiple stimulation levels for breast massage, and multiple milk suction speeds and intensities to imitate the rhythm and

quantity of a baby's suction. The keyboard of the device control panel is soft. The screen is an LCD, and allows for process viewing.

Indications for Use:	The electric breast pump is intended to express and collect milk from the mother's breast, to alleviate engorgement of the breast, maintain the ability of lactation, and provide mother's milk for future feedings when separation of mother and baby occurs. The device is intended for a single user, not for hospital use.
Technology:	The electric breast pump has an electric negative pressure module (one/two set of core vacuum pump) which utilizes automatic control system comprising a single-chip microcomputer and control procedure to set and adjust the mode, velocity and intensity of stimulation and suction. The core module vacuum pump runs discontinuously to generate periodic negative pressure, and to control another critical component, a magnetic valve, to adjust negative pressure periodically.

Determination of Substantial Equivalence:

Table 5.1 Comparison with Predicate Device

Specification	Predicate Device	Proposed Device
Device name	**LANSINOH Powered Electric Breast Pump**	**Electric Breast Pump**
K number	**K122474**	**K143585**
Indications for Use	The powered breast pump is intended to express and collect the breast milk of a nursing woman for the purpose of feeding the collected milk to a baby. The Powered Breast Pump is intended for a single user.	The electric breast pump is intended to express and collect milk from the mother's breast, to alleviate engorgement of the breast, maintain the ability of lactation, and provide mother's milk for future feedings when separation of mother and baby occurs. The device is intended for a single user, not for hospital use.
Patient Population	Breastfeeding women	Breastfeeding women
Pump Style	Diaphragm-type vacuum pump	Diaphragm-type vacuum pump
Stimulation velocity	93～144 T/min	95～105 T/min
Stimulation intensity	-0.007～-0.019MPa	-0.002～-0.019MPa
Sucking velocity	36.6～91.2 T/min	20～65 T/min
Suction intensity	-0.011～-0.029 MPa	-0.011～-0.033 MPa
Backflow protection	Yes	Yes
Overflow protection	No	No
Adjustable Suction Levels	Yes	Yes
Software	Yes	Yes
Anatomical Sites	breast	breast
Environment of Use	Hospital, institutions and home	Home and not for hospital use

Summary of Non-Clinical Tests:

The sponsor has performed bench tests to demonstrate the electric breast pump of six models performs within specifications.
Also, the proposed device has met acceptance criteria of performance testing including biocompatibility (in vitro cytotoxicity, irritation and sensitization testing), electrical safety, and EMC testing. There are no differences between the subject and predicate devices that affect the safety and effectiveness.

Summary of clinical tests:

The subject of this premarket submission, electric breast pump, did not require clinical studies to support substantial equivalence.

Conclusion: Shantou Xinghe Electrical Apparatuses Ltd. considers the electric breast pump to be as safe and effective as the predicate. Electric Breast Pump is therefore substantially equivalent to the predicate device.